AUG 0 8 2002

K022426

Attachment 4

510(k) Summary of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: BD Vacutainer Systems, PreAnalytical Solutions
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: M. Wendy Bosshardt
  Regulatory Affairs Specialist
  Telephone no.: 201-847-6280
  Fax No. 201-847-4858
- Date of Summary: July 22, 2002

Device

- Trade Name: BD Preset™ and BD A-Line™ Blood Collection Syringes
- Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting Substantial Equivalence

- Device Description

The BD Preset™ and BD A-Line™ Blood Collection Syringes are sterile, single use devices designed to collect whole blood specimens for diagnostic testing.

➢ BD A-Line™ Blood Collection Syringe is specifically designed for aspiration of blood samples from arterial lines.

➢ BD Preset™ Blood Collection Syringe is a specifically designed (may include needle) that can be preset to a desired volume, but permits aspiration when necessary. Includes a venting system that expels residual air through the self-venting membrane (as blood fills the syringe), which ensures rapid filling.

- Intended Use

The BD Preset™ and BD A-Line™ Blood Collection Syringes are intended to collect whole blood specimens for diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium), metabolytes, co-oximetry, and other tests.

- Synopsis of Performance Study Results

Performance studies were done to show the performance and equivalence of the principal devices to the predicate devices currently marketed in the United States.

All results from the studies show equivalence between the principal devices and the predicate devices. Therefore, the BD Preset™ and BD A-Line™ Blood Collection Syringes are substantially equivalent to the predicate devices.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the device features, materials, intended use and performance, the BD Preset™ and BD A-Line™ Blood Collection Syringes are shown to be substantially equivalent to the commercially available predicate devices indicated in the table below. The predicate devices, K number, and clearance date are also identified in the table below.

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson	VACUTAINER™ Brand Blood Collection Syringes	K982922	Sept. 22, 1998

M. Wendy Bosshardt

M. Wendy Bosshardt
Regulatory Affairs Specialist
Becton Dickinson VACUTAINER Systems
Becton Dickinson and Company

July 22, 2002
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 0 8 2002

Ms. M. Wendy Bosshardt
Regulatory Affairs Specialist
Becton, Dickinson and Co.
1 Becton Drive
Franklin Lakes, NJ 07417

Re: k022426
Trade/Device Name: BD Preset™ and BD A-Line™ Blood Collection Syringe
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code:. JKA
Dated: July 22, 2002
Received: July 25, 2002

Dear Ms. Bosshardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number
(if known)

Device Name BD Preset™ and BD A-Line™ Blood Collection Syringe

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Indications for Use

BD Preset™ and BD A-Line™ Blood Collection Syringe are intended to collect whole blood specimens for diagnostic testing which may include: pH, blood gases, electrolytes (including ionized calcium), metabolytes, co-oximetry, and other tests

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Device

510(k) Number K022426

Prescription Use ✓ OR Over-The Counter Use_____
(per 21 CFR 801.109)